



xShare Open Call 2025: Enabling Interoperable Health Data Sharing Across Europe

10 November 2025





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Expanding the European Electronic Health Record Exchange Format (EHRxF)

to share and effectively use health data within the European Health Data Space (EHDS)

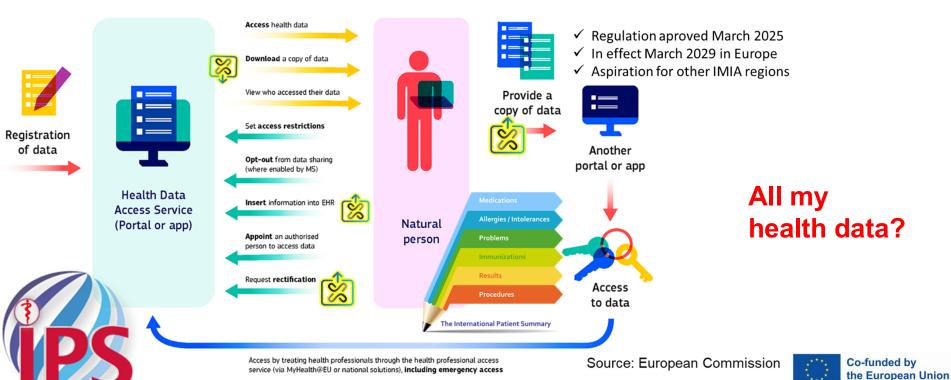


Catherine Chronaki, HL7 Europe
Technical Coordinator



EHDS: placing patients at the center of their health and care





xShare...





..Expanding the European EHRxF to



share and effectively use





health data within the EHDS



xShare "Yellow" Button Vision



Click 'n share their health data in EEHRxF at click-of-a-button





One-time share



Linked options





















Contact xShare: info@xshare-project.eu









HL7 FHIR IGs overview work in progress

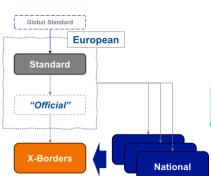


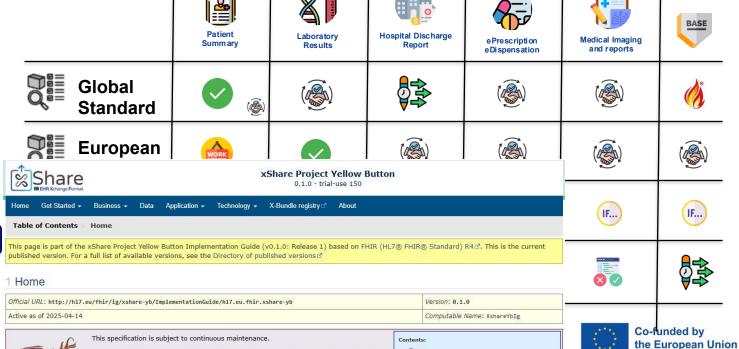
Scope

Purpose
 Get Started

· Understand this Guide







Revisions and extensions may be introduced over time, including updates to the business

Readers should be aware that changes may occur and are encouraged to stay

scenarios and to the reference technical specification.

informed about the latest developments.

Recipients of the experimental xShare Industry Label 2025





Visit the xShare Dashboard here:

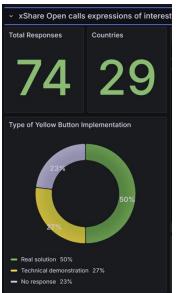






With its open calls, the xShare Button Movement drives innovation









https://xshare-project.eu/news/xshare-open-call-2025-call-for-early-adopters-of-the-xshare-yellow-button/



Vision: Everyone can effortlessly share their health data in the European EHRxF with just a click-of-a-button.







Key Points

- **xShare Button & Label:** ser-friendly feature across health portals and apps.
- **Data Portability:** Empowering people to exercise GDPR rights, in trust & flow.
- European Electronic Health Records Exchange Format (EEHRxF) Impact: Fosters citizen (and patient) engagement, driving research and innovation in the EHDS.
- **Digital Compass 2030:** EU's vision for a human-centred, sustainable digital future.



Benefits

- Simplifies sharing of trusted health data and fosters citizen science
- Strengthens digital resilience.
- Advances global leadership in digital health standards.











Why Join the open call of Early Adopters of the xShare button?





Get ready for EHDS, with HL7 FHIR knowledge

- Implement the Yellow Button
- Test the Yellow Button online or in Person
- Receive the xShare Industry Label



Join EUCROF code of conduct for GDPR



Get support from HL7 FHIR experts



Be recognized for your efforts



Opportunity to be selected for funding



Let's innovate!



What are the next steps?



Once you apply we reach out for an interview

You start implementation of the selected use cases

We support you with the adoption kit under development

- Specifications
- Sample data
- Online testing tools
- Community meetups
- Helpdesk
- Online videos



Present your solution and be recognized for innovation





Let's innovate!





xShare Open Call

Yoanni Th. Matsakis



Purpose of the Open Call

Practical implementation of business use cases inspired by the identified BUCs demonstrating the benefits of a wide dissemination of the EHDS standards (EEHRxF, IPS+).



Who can apply?

All affiliated members of EUCROF (therefore service providers for clinical research or "CRO"), either alone or in consortium with other stakeholders of clinical research such as hospital sites involved in clinical research or networks of hospital sites or other academic players, private players (pharma, biotechs, medtechs ...).



Eligibility criteria

The candidate CRO must be affiliated with EUCROF and engaged in adhering to the EUCROF GDPR Code of Conduct for Service Providers in Clinical Research (EUCROF GDPR Code or Code) and therefore be listed in the public registry

More about the Code: https://eucrof.eu/gdpr-code-of-conduct/

Public Registry: https://cro.eucrof.eu/eucrof-code-public-registry

- The proposed demonstration project must fall within the purpose of the open call: see the 10 business cases detailed in the appendix I. The proposal shall clearly identify to which business case the proposal refers (see also the foot note)
- The proposal should include a convincing plan for evaluating how the implementation of the EHDS standards will facilitate future scale-up of the business case.

Note: proposals may also refer to other business cases than the ones listed in the appendix and such a case the proposal shall provide evidence that the BUC fully complies with the purpose



What are the benefits?



All proposals could have a "poster" exposed at EUCROF26 and be presented by means of short videos in LinkedIn

Exposure through social media and web sites

The proposals with the best rank will get a financial "support" from EUCROF.

Industry xShare label will be awarded to the successful proposals

EHDS readiness for your company

Priority to get the adherence mark to the EUCROF Code of Conduct for Service Providers in Clinical Research (approved 12 Sept. 2024 by the 27 EU Member States Data Protection Authorities



Awards and Financing







Bronze Award: participation to the EUCROF conference with posters and dedicated follow-up to adhere to the Code

- Results will be announced at the EUCROF26 Conference in Amsterdam (1-3 February 2026), during the evening event
- A total budget of 120kEUR is positioned to finance the implementation phase (post award). A service contract will be signed and the budget allocated depending on implementation needs and assessment criteria

 Co-funded by the European Union

Business Use Cases (all "eligible")

Nb	Description	Scope
1	Patient pre-screening in clinical trial through a SAREC healthcare professional tool	Prescreening
2	Patient self-nomination as possibly eligible for a trial	Prescreening
3	Protocol feasibility via a repository of IPS+R summaries, e.g. at hospital, regional or national level	Feasibility
4	Targeted patient recruitment via a repository of IPS+R summaries, e.g. at hospital, regional or national level	Prescreening
5	Clinical Study support – whole scenario (side effect reporting)	Study support
6	Longitudinal cohort tracking	Cohort
7	Clinical Study definition	Study support
8	Clinical Study follow-ups	Study support
9	Site feasibility guided by xShare Button	Feasibility
10	eCRF Filling Process - Support for data collection of a health study	Study support



Examples of potential "implementations" (1/2)

Patient Matching Portal for Clinical Studies

A commercial platform connects patients with investigational sites, currently hosting 40,000 registered patients.

A planned feature allows patients to upload IPS+ data for automated study matching instead of manual questionnaires.

Due to the unavailability of real IPS+ data before project completion, mock datasets will be used for testing.

While innovative, this work has no immediate societal impact but holds potential for recognition.



Examples of potential "implementations" (2/2)

<u>Automating Data Transfer for Patient Registries</u>

A high number of hospitals participate in registries, with physicians requesting integration between hospital EHRs and eCRFs to reduce double entries.

A standardized framework has been developed to enable automated data transfer from EHRs to eCRFs.

Initial implementation in 20 hospitals with one registry, ensuring scalability.

In his personal space (ePRO or eConsent), the patient can click the xShare button and download his IPS+

Future adoption of EEHRxF will further streamline the process.

Over 1,000,000 eCRFs potentially impacted.



How to apply

1. Complete the application form

Express your interest in participating by filling in this form.

2. Prepare your outline proposal

Review the present guidelines and ensure your project aligns with the objectives.

3. Submit your application before December 15th, 2025

Send the outline proposal at xshare@eucrof.eu







Open Calls - Assessment Framework Christophe Maes



Assessment and evaluation framework



Application process



Eligibility criteria

Core Impact and Feasibility Criteria

- 1. Business Use Case Correspondence
- 2. Patient Impact Potential
- 3. Healthcare-Professional Efficiency Gains
- 4. xShare "Yellow Button" Implementation Quality
- 5. Solution Quality Management & Maturity
- 6. Replication Power across Europe
- 7. EHDS & EEHRxF Awareness and Adoption
- 8. EUCROF Code & Data-Protection Compliance
- 9. Built-In Lessons Learned Process
- 10. Effectiveness of Business Case Implementation



Usability and accessibility evaluation Criteria



Assessment committee and decision-making procedure





- xShare Scientific Leader: Catherine Chronaki
- Representative of MedCom: Janne Rasmussen
- Representative of xShare WP5 and COSUP vice-chair: Christophe Maes
- Representative of the Pharmaceutical/Biotechnology Sector: Nadir Ammour
- Representative of Investors: TBD
- Representative of the Scientific Committee of EUCROF26: TBD

🖄 Observer

 EUCROF Observer with no assessment and decision rights: Yoanni Matsakis



Assessment committee and decision-making

Share Share Format

procedure

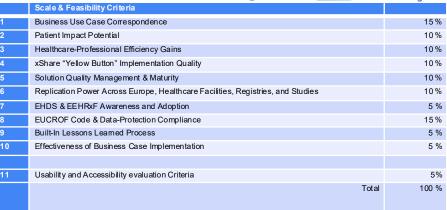


Eligible Criteria



Scoring Scale feasibility and Impact criteria

Weighting Factors





Decision Thresholds

- O Highly Recommended: overall score ≥ 80 percent.
- **Recommended, Subject to Clarifications**: overall score ≥ 70 percent and < 80 percent.
- Not Recommended: overall score < 70 percent.
- Notwithstanding the foregoing, any proposal scoring below 2/5 on a critical Criterion shall be automatically disqualified, regardless of its overall percentage.



Final decision



Award – EUCROF conference Amsterdam 1 – 3 February 2026



Assessment and evaluation framework



After being awarded

- Technical Conformity Assessment third party
 - Home xShare Project IPS+ v0.1.0
 - https://x-bundles.ehr-exchange-format.eu/
- Use Case specific DPIA
 - Data flow / Architecture
 - xShare Label (where applicable)

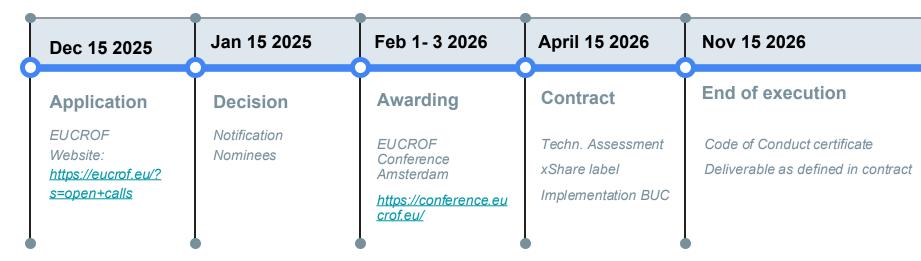
https://xshare-project.eu/xshare-industry-label/

- Bronze
- Silver
- Gold
- EUCROF CoC certificate COSUP





Timeline Open Calls





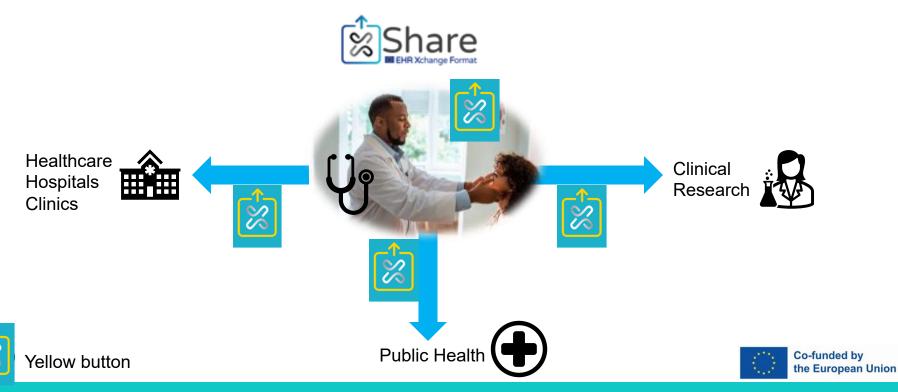


International Patient Summary Plus (IPS+)

Dipak Kalra Rebecca Baker



Sharing Data with the xShare Yellow Button and the Patient at the Center Supporting Primary and Secondary use



International Patient Summary (IPS)

Health, healthcare, cross-border care



International Patient Summary Plus (IPS+)

Public Health, Clinical Research, etc.

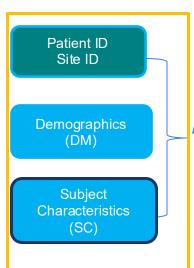


Clinical Research Objectives

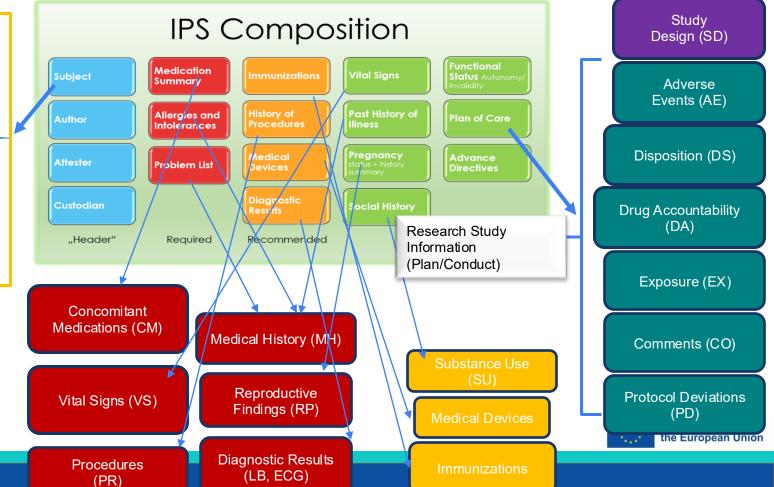


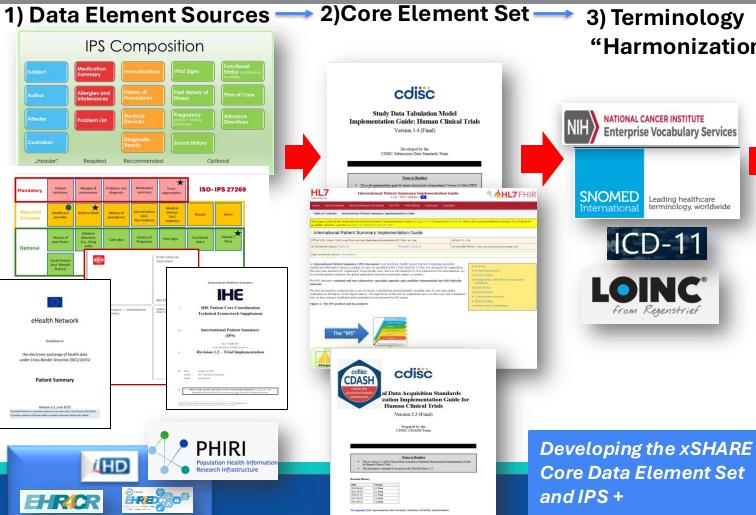
- Carry out business use case analysis to identify clinical research use cases leveraging real world EHR data.
- Carry out gap analysis to determine the extent to which the EEHRxF (mainly the IPS) would be sufficiently rich to deliver value to these use cases.
- Identify modest candidate data set extensions to the IPS and propose a new HID, the EHRxF IPS + .
- Develop necessary research extensions to IPS + and CDISC, to resolve gaps as needed.
- Test, demonstrate, and validate data availability, quality and utility of IPS + in real world data sets.
- Engage patients in accessing and using the IPS + through an open call to EUCROF members















NEXT STEPS (Putting the **Core Data Element Set** into Use):

Consensusbuilding, Validation in **New Health** Information **Domains** (HIDs), e.g., **IPS+BUC, Care** Plans, Telemonitoring, **Public Health**

DOMAIN/CATEGORY: IPS-Subject = CDISC-Demographics (DM) **Subject Characteristics (SC)**

- > Subject Characteristic / Demographic Item
- Subject Characteristic/Demographic Result
- Collection Date

Demographics/Subject Characteristics - Specific Requested Items:

- Research Subject Identifier
- Research Study Identifier
- ➤ Age
 - Age Units
- Birth Date
- Gender/Sex*
- Death
 - Death Date
 - Death Time
 - Subject Death Flag

IPS-Problem List = CDISC- Medication History (MH)**

- Problem/Condition/Medical History Reported Term
- · Medical History Event Collection Date · Medical History Event Start Date
- · Medical History Event End Date
- Hypertension
- Diabetes
- · Chronic obstructive pulmonary disease
- Alcohol Abuse
- Drug Abuse
- Allergy

IPS-History of Procedures = CDISC- Procedures (PR)

- Name of Procedure
- Procedure Start Date
- Procedure Indication

DOMAIN/CATEGORY:

IPS Diagnostic Results= CDISC- Laboratory Results (LB) Microbiology Results (MB); Body Systems Findings**

- Diagnostic/Laboratory/Micro Test Name
 - Diagnostic/Lab/Micro Result in Original Units Value
 - Diagnostic/Lab/Micro Original Units
 - ➤ Diagnostic/Lab/Micro Specimen Collection Date
 - Diagnostic/Lab/Micro Specimen Collection Time
 - Diagnostic/Lab/Micro Specimen Type
 - Diagnostic/Lab Fasting Status
 - Diagnostic/Lab/Micro Specimen/Reference ID
 - > Lab Ref Range Lower Limit in Original Unit
 - > Lab Ref Range Upper Limit in Original Unit
 - ➤ Diagnostic/Lab/Micro Specimen Collection Location
 - Diagnostic/Lab/Micro Method of Test/Exam
 - > Microbiology Examination Detail

IPS-Medication Summary = CDISC- Concomitant Meds (CM)

- Medication/Drug/Product Name
 - > Medication Start Date
 - > Medication End Date

 - Dose Form

 - Medication Indication

IPS- Pregnancy status + history summary = CDISC- Reproductive Findings (RP)

- Reproductive Original Orias
 Reproductive System Finding Date
 There are a number of discrete pregnancy related outcomes that were mapped to CDISC SDTM since there were discrete data elements in IPS (code system/code/label) available potential public health use case

IPS-Vital Signs = CDISC- Vital Signs (VS)

- Vital Signs Test Name
- Vital Signs Date Vital Signs Time
- Vital Signs Result of Finding in Original Units
- Vital Signs Original Units

IPS-Social History = CDISC- Substance Use (SU)

- Substance Dose

PS-Data Element = Adverse Event** CDISC- Adverse Events (AE)

Allergies and Intolerances

- Start Date

DOMAIN/CATEGORY:

IPS-Data Element = CDISC- Healthcare Encounters (HO)

- Hospital Stay
 - Admission Date
 - **Discharge Date**
 - **Healthcare Encounter**
 - Reason for Healthcare Encounter
 - Reported Term for Healthcare Encounter
 - **Healthcare Encounter Start Date**
 - **Healthcare Encounter End Date**

Category Not in HL7 FHIR IPS IG ISO IPS and IPS IHE have discharge summary information

Note: Items in black are proposed to add to IPS to support secondary use.

Title: General Medical History	IPS DE IPS Comp Cat		t CDISC Domain	CDISC Variable		CDISC Variable Label		
Indicate if the subject experienced any medical conditions or events. If Yes, include the appropriate details where	Has the subject had any medical conditions or events? MHYN Not Submitted Medical History Category MHCAT Pre-populated	○ Yes ○ No < NY codelist >	Diabetes	Problem List	МН	MHTERM; MHD	DECOD	Reported Term for the Medical History; Dictionary-Derived Term
indicated on the CRF.			Hypertension	Problem List	МН	MHTERM; MHD	DECOD	Reported Term for the Medical History; Dictionary-Derived Term
		Sponsor Define	Chronic obstructive pulmo	Problem List	МН	MHTERM; MHD		Reported Term for the Medical History; Dictionary-Derived Term
			Acute myocardial infarction	r Problem List	МН	MHTERM; MHD		Reported Term for the Medical History; Dictionary-Derived Term
Sponsor-Defined CRF Completion Instructions	What is the medical condition or event identifier?		FHIR Path Origin		SDTM Variable(s)	MedDRA	MedDF	RA Preferred Term
						Code		
Record all relevant medical conditions or events, as defined	What is the medical condition or event term? MHTERM		Condition.code Condition.onsetDateTime Condition.code Condition.code		MHDECOD	10012601	012601 Diabetes mellitus	
in the protocol. Record only one medical condition or event					MHSTDTC			
per line. Ensure that the medical conditions or events listed					MHTERM			
on the Medical History page do not meet any of the exclusion criteria.					MHDECOD	10020772	Hypertension	
Consist Citation			Condition.onsetDate	Гime	MHSTDTC			
Record the start date of the medical event or condition	Start Date		_		MHTERM			
using this format (DD-MON-YYYY).	HSTDAT MHSTDTC		Condition.code		MHDECOD	10009033	Chronic	obstructive pulmonary disease
Record the medical condition or event as ongoing (Yes) if it	Is the medical condition or event ongoing?	○ Yes	Condition.onsetDateTime		MHSTDTC			
has not ended at the time of data collection; the end date should be left blank. MHONGO MHENRE/ MHENRETT		○ No < NY codelist>						
Record the end date of the medical event or condition using this format (DD-MON-YYYY).	End Date MHENDAT MHENDTC							The question

For medical history, the term is as collected. It is then standardized using MedDRA codes.

Medical History Condition in SNOMED = 404684003 – Clinical Finding

73211009
Diabetes mellitus (disorder)

The answer

IPS Category CDISC Domain

Data Element NCIt C-Code SNOMED Code -Question SNOMED Code -Answer USCDI v4.0 Data Element CDASHIG Variable Label

CDASHIG Definition

xShare Core Harmonized Data Elements

CDASH Question Text

CDASH Prompt CDISC Codelist

S Category	Domain	Data Element	NCIt C-Code	SNOMED Code- Question	SNOMED Code-Answer	USCDI v4.0	CDASHIG Variable	CDASHIG Variable Label	DRAFT CDASHIG Definition	Question Text	Prompt	Codelist	
						Member Identifier (Patient Identifier-							
						would link to the research subject in							
						blinded fashion at site level only known to			A unique subject identifier within a site and	What [is/was] the (study)			
abject .	DM	Research Subject Identifier for the study		No code	No code	investigator and team)	SUBJID	Subject Identifier for the Study	a study.	[subject/participant] identifier?	[Subject/Participant] (Identifier)		
ıbject	DM	Study Site Identifier	C83081	No code	No code	N/A	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)		
									Identifier used to uniquely identify a				
									subject across all studies for all				
									applications or submissions involving the				
									product. This must be a unique value, and				
									could be a compound identifier formed by				
								Unique Subject Identifier for the	concatenating	What [is/was] the (StudyID)-(SiteID) (study)			
ubject	DM	Research Unique Subject Identifier	C69256	No code	No code	N/A	USUBJID	Study	STUDYID-SITEID-SUBJID.	[subject/participant] identifier?	[STUDYID-SITEID-SUBJID]		
ubject	DM	Research Study Identifier	C83082	No code	No code	N/A	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]		
				424144002 Current chronological					The age of the subject, expressed in				
ubject	DM	Age	C170981	age (observable entity)	No code	N/A	AGE	Age	AGEU.	What is the subject's age?	Age		
									Units of time routinely used to express the				
ubject	DM	Age Units	C50400	258707000 year (qualifier value)	No code	N/A	AGEU	Age Units	age of a person.	What is the age unit used?	Age Unit	C66781	
									The date of collection, represented in an				
									unambiguous date format (e.g., DD-MON-				
ubject	DM	Demographics Collection Date	C83243	Information model	No code	N/A	DMDAT	Demographics Collection Date	YYYY).	What is the date of collection?	Collection Date		
				184100006 Patient sex (observable	< 429019009 Finding related to				Sex of the subject, as determined by the				
ubject	DM	Sex (Administrative/clinical use?)	C28421	entity)	biological sex (finding)	Sex	SEX	Sex	investigator.	What is the sex of the subject?	Sex	C66731	
									A subject's date of birth (with or without the				
									time of birth). The complete Date of Birth is				
									made from the temporal components of				
				184099003 Date of birth (observable					Birth Year, Birth Month, Birth Day, and				
ubject	DM	Birth Date	C83217	entity)	No code	Date of Birth	BRTHDAT	Birth Date	Birth Time	What is the subject's date of birth?	Birth Date		
									Date/time of death for any subject who				
									died, in ISO 8601 format. Should represent				
				399753006 Date of death					the date/time that is				
ubject	DM	Deceased Date	C117450	(observable entity)	No code	Date of Death	DTHDTC	Date/Time of Death	captured in the clinical-trial database.	What was the subject's date/time of death?	Death Date		
					410515003 Known present				Indicates the subject died. Should be "Y"				
				18632008 Patient status	(qualifier value)				or null. Should be populated even when				
ubject	DM	Deceased Flag	C117451	determination, deceased (finding)	410516002 Known absent	N/A	DTHFL	Subject Death Flag	the death date is unknown	Was the subject dead?	Subject Death Flag	C66742	
						Data included for individual patient							
						information; Physical Activity; Sexual							
					363790008 General	Orientation; Gender Identity; Preferred							
				363789004 General characteristic of		Language; Occupation; Occupation			Descriptive name of the subject				
ubject	SC	Subject Characteristic	C103330	patient (observable entity)	(observable entity)	Industry	SCTEST	Subject Characteristic	characteristic of interest.	What is the subject characteristics name?	[Subject Characteristic Test Name]	C103330	
									The date of collection represented in an				
								Subject Characteristic Collection	unambiguous date format (e.g., DD-MON-				
ubject	SC	Subject Characteristic Collection Date	C83397	Information model	No code	N/A	SCDAT	Date	YYYY).	characteristics were collected?	Date		
				This could be a value set, but no					Result of the subject characteristic as				
ubject	SC	Subject Characteristic Finding Value	C83107	individual code	No code	N/A	SCORRES	SC Result or Finding in Original Units		What is the subject characteristic?	(Result)		
				This could be a value set, but no			[SCTESTCD]_SCORRE		Result of the subject characteristics as				
ubject	SC	Subject Characteristic Finding Value Units	C83400	individual code	No code	N/A	S	SC Result or Finding in Original Units		What is the subject's [SCTEST]?	[SCTEST] Result		
				1003642006 Past medical history	< 404684003 Clinical finding	Problem (Condition, diagnosis, or reason		Reported Term for the Medical	The reported or prespecified name of the	What is the medical condition or event			
oblem List	MH	Medical History Reported Term	C83118	section (record artifact)	(finding)	for seeking medical attention)	MHTERM	History	medical condition or event	term?	Medical History Term		

Terminology Perspectives for Adoption Sites







- Allows clinicians to use any appropriate code
- IPS valuesets can be over 1000 terms
- SNOMED has browser tools to aid clinicians to identify the terms (and codes) needed for clinical care documentation



Supports flexibility for precise clinical documentation



Defined, limited codelists

OPTION 2

- Provides smaller, predefined set of terms and codes
- Ensures researchers use consistent terminology when designing study forms regardless of format

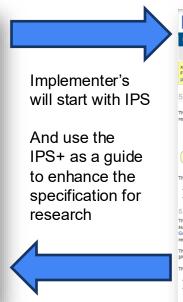


Promotes interoperability and rigor required for clinical research

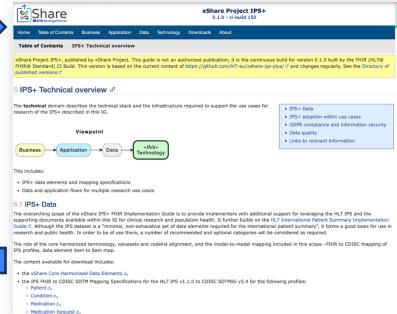


HL7 FHIR International Patient Summary





xShare IPS+ provides tools to implement the HL7 IPS for clinical research and public health



Tools in IPS+

nion

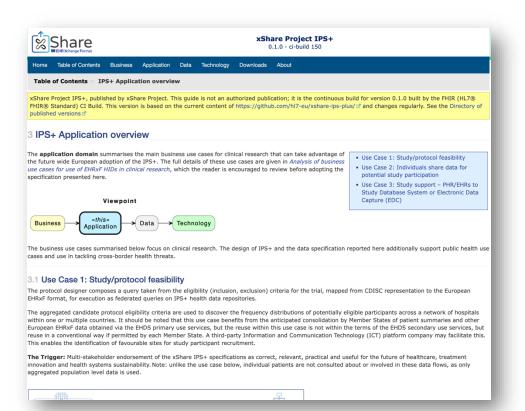
Use Cases

Study/protocol feasibility

Through federated queries on repositories of IPS+ summaries, e.g. at hospital, regional or national level

- Potential study participation
 - Individuals explore potential clinical studies by leveraging their up-to-date IPS+ health data through a PHR via the xShare Yellow Button
- Study support

Research question responses and eCRF filling







User Acceptance

Mario Fregonara Medici



Accessibility & Usability for Healthcare Applications

Digital accessibility is an important aspect of the EU commitment to inclusion of diversity and creating a 'Union of equality'.

All online services and digital information provided by public sector bodies (including healthcare organizations) across the EU must be accessible to all persons, regardless of ability, which is essential for an inclusive society (with the "Web Accessibility Directive" - applicable since 2021).

 Goal: Ensure digital health tools are usable, safe, and inclusive for all patients and clinicians



Why it matters

- Patient safety: reduce errors and misinterpretation
- Legal compliance: regulatory risk mitigation
- Health equity: it includes older adults and people with disabilities
- Poor usability: it causes missed care and abandonment
- Business impact: lower support costs, higher adherence



EU legislation

- The "Web Accessibility Directive" (WAD) obliges all EU public sector bodies (including healthcare organizations) to make their online services, website information and mobile apps accessible to all persons, regardless of ability.
- The "European Accessibility Act" (EAA) is applicable since 28 June 2025. It establishes common accessibility requirements for "general" online products and services to be accessible to persons with disabilities and elderly people.
- The EAA requirements are complementary to the WAD in general terms.
- The main European standard supporting implementation of both directives is EN301549.



Core principles

- Adopt POUR: Perceivable, Operable, Understandable, Robust
- User-centered design, including research activities
- Privacy and clinical safety by design and default
- Better clinical outcomes

People and contexts

- Diverse users: vision, hearing, motor, cognition, language, digital literacy
- Different care scenarios: clinic, bedside, emergency, home
- Different technology contexts: connectivity bandwidth, number and type of medical devices
- Deliverable: 4–6 personas in the Business Use Case scenarios



User interface and experience specifications

- Clear information hierarchy and necessary settings
- Simplified workflows for time-critical tasks
- Inline validation, error prevention, and recovery paths
- Progressive disclosure for non-critical details

Clinical safety requirements and usability

- Alert prioritization to reduce fatigue
- Confirmations for high-risk actions, data or setting changes and override logging
- Avoid ambiguous labels (e.g.: medication and dosing flows)
- Audit trails for traceability and incident review





Technical Requirements

Peter Casteleyn



Technical requirements





Initiatives should follow as much as possible the IPS+ Implementation Guide

- IPS+ required for all use cases
- Technology architecture for use cases BUC2. BUC3 and BUC10



xShare Project IPS+ 0.1.0 - ga-preview 150

Application

Table of Contents

This page is part of the xShare Project xShare Project IPS+ Implementation Guide (v0.1.0: QA Preview) based on FHIR (HL7® FHIR® Standard) R4. This is the current published version. For a full list of available versions, see the Directory of published versions

1 Home

Official URL: http://hl7.eu/fhir/ig/xshare-ips-plus/ImplementationGuide/hl7.eu.fhir.xshare-ips-plus Version: 0.1.0 Draft as of 2025-10-14 Computable Name: XshareipsplusIq



The specification herewith documented is a working specification. No liability can be inferred from the use or misuse of this specification, or its consequences.

Contents:

- Scope
- Purpose
- · How to read



Implementation Guide link: https://hl7.eu/fhir/ig/xshare-ips-plus/

1.1 Scope

This guide provides instructions to help you understand and implement your product in accordance with the xShare IPS+, facilitating in the access and adoption of the selected specifications.

1.2 Purpose

This FHIR Implementation guide is designed to assist users in implementing the International Patient Summary for secondary data purposes, such as clinical research and public health. The xShare specification informs the FHIR International Patient Summary and this is referred to as IPS+. The aim is to solve the existing challenge created by the variability and semantic differences in health data. Addressing this issue successfully will help create a consistent and reliable health data system. improving public health and wellness and to enable clinical recearch, the results of which can inform healthcare decisions in a learning health system. It will also give

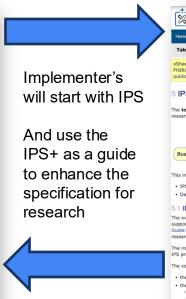


Implementation Guides

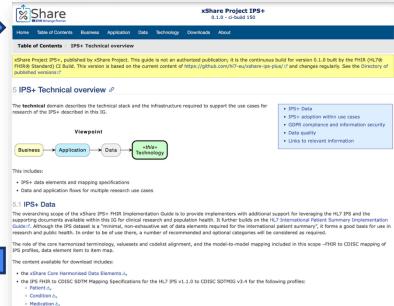


HL7 FHIR International Patient Summary





xShare IPS+ provides tools to implement the HL7 IPS for clinical research and public health



Tools in IPS+

nion

FHIR to CDISC Map

Core Harmonized Dataset

Value set alignment

Medication Request ₺,

Workflow to Trigger IPS+

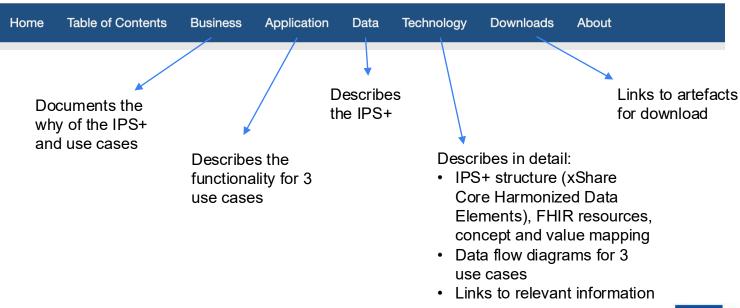
Implementation Guide - structure





xShare Project IPS+

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IPS+ - to be used in all use cases



© Core Harmonized Data

FHIR – CDISC SDTM mapping for IPS+ (example Observation Results Lab)

SNOMED, LOINC mappings (subsets)

IP Cate	S gory	CDISC Domain	. 1	Data Element	NC C-Co	lt Co	MED de - estion	SNOMEI Code - Answer	USCD v4.0 Da Elemei	ita Varia	able	CDASH Definiti
	χS	Share C	ore	Harmo	onized	l Data E	lem	ents	CDASI Questio			CDIS:
									Text			
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the IPS FHIR to CDISC SDTM Mapping Specifications for the HL7 IPS v1.1.0 to CDISC SDTMIG v3.4 for the following profiles:

In the description SDTM is the tabulation source for CDISC. The mapping is from FHIR to CDISC SDTM

This is the README for the StructuredDefiniti

Condition ♣,
 Medication ♣.

Medication Request

• Medication Request

Medication StatemeObservation Results

∘ Procedures ₺,

∘ Diagnostic Report **±**

Allergy and Intolleration

Immunization ±,
 the base R4 FHIR re

Tab	Topic	Description
Metadata	Original IPS Specification	http://ht7.org/fhir/uv/ips/StructureDefinition-Observation-results-laboratory-uv-ips.html
Elements	Original IPS Specification	http://hl7.org/fhir/uv/ips/StructureDefinition-Observation-results-laboratory-uv-ips.html
Elements_IPS Generic Lab - SDTM	Original IPS Spec to SDTM	Element tab from original IPS-Observation-results-laboratory to SDTM - written using the LB domain to aid understanding. Applicable to all specimen domains changing the two letter domain code and the test terminology to match that domain.
Lab Result Profile to SDTM	Brief source to target FHIR to SDTM specificallly for the LB domain	Lab result FHIR Path to SDTM using the LB domain to aid comprehension
IPS Generic Lab Result to SDTM	Brief source to target FHIR to SDTM providing a generic perspective	Lab result FHIR Path to SDTM using the "" for the laboratory domain referencing the "Determining the domain" tab for guidance on how to determine the SDTM domain.
Determining the domain	How to determine the CDISC SDTM Findings domain	Provides guidance to determine the domain for the observation of the mapping.
Specimen Findings Domains	How to determine the Laboratory Findings domain related to the specimen of the observation.	Provides guidance to determine the domain for the observation of the mapping for laboratory specimens.
Common Rules	Rule or guidance that applies to all mappings regardless of the topic or object	Provides guidance for mapping from FHIR to CDISC SDTM for all content. This content applies to all doma plated across all maps when updates applied.

- resourceTypeConceptMap CDISC to SNOMED.txt
- resourceTypeConceptMap_LOINC_to_SNOMED.txt
- resourceTypeConceptMap_SNOMED_to_CDISC.txt
- resourceTypeConceptMap_SNOMED_to_LOINC.txt



Use Cases

Study/protocol feasibility

Through federated queries on repositories of IPS+ summaries, e.g. at hospital, regional or national level

Potential study participation

Individuals explore potential clinical studies by leveraging their up-to-date IPS+ health data through a PHR via the xShare Yellow Button

Study support

Research question responses and eCRF filling



xShare Project IPS+

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e Table of Contents Business Application Data Technology Downloads About

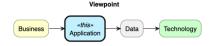
Table of Contents > IPS+ Application overview

This page is part of the xShare Project xShare Project IPS+ Implementation Guide (v0.1.0: QA Preview) based on FHIR (HL7® FHIR® Standard) R4. This is the current published version. For a full list of available versions, see the Directory of published versions

3 IPS+ Application overview

The application domain summarises the main business use cases for clinical research that can take advantage of the future wide European adoption of the IPS+. The full details of these use cases are given in Analysis of business use cases for use of EHRXF HIDs in clinical research, which the reader is encouraged to review before adopting the specification presented here.

- Use Case 1: Study/protocol feasibility
- Use Case 2: Individuals share data for potential study participation
- Use Case 3: Study support PHR/EHRs to Study Database System or Electronic Data Capture (EDC)



The business use cases summarised below focus on clinical research. The design of IPS+ and the data specification reported here additionally support public health use cases and use in tackling cross-border health threats.

3.1 Use Case 1: Study/protocol feasibility

The protocol designer composes a query taken from the eligibility (inclusion, exclusion) criteria for the trial, mapped from CDISC representation to the European EHRxF format, for execution as federated queries on IPS+ health data repositories.

The aggregated candidate protocol eligibility criteria are used to discover the frequency distributions of potentially eligible participants across a network of hospitals within one or multiple countries. It should be noted that this use case benefits from the anticipated consolidation by Member States of patient summaries and other European EHRxF data obtained via the EHDS primary use services, but the reuse within this use case is not within the terms of the EHDS secondary use services, but reuse in a conventional way if permitted by each Member State. A third-party Information and Communication Technology (ICT) platform company may facilitate this. This enables the identification of favourable sites for study participant recruitment.

The Trigger: Multi-stakeholder endorsement of the xShare IPS+ specifications as correct, relevant, practical and useful for the future of healthcare, treatment innovation and health systems sustainability. Note: unlike the use case below, individual patients are not consulted about or involved in these data flows, as only aggregated population level data is used.

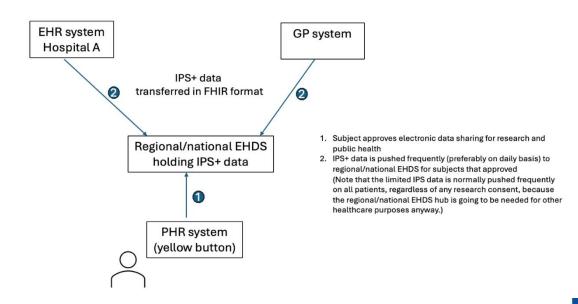


Detailed use cases - data flows (1/3)





The use cases described in the following paragraphs rely on the base setup as described in this simplified figure.





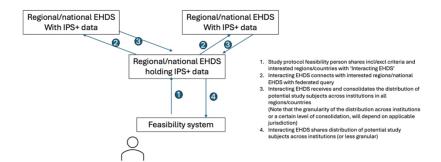
Detailed use cases - data flows (2/3)





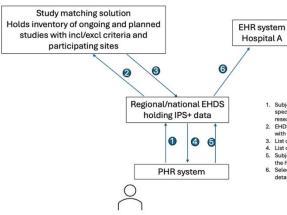
Study/protocol feasibility (BUC2)

A simplified flow noting the environments used is described in the following figure:



Individuals share data for potential study participation (BUC3)

A simplified flow noting the environments used is described in the following figure:



- 1. Subjects indicates interest in joining ongoing studies for a specific TA (pre-requisite: given approval for data sharing for
- 2. EHDS shares patient IPS+, interested TA and subject location with study matching solution
- 3. List of studies and nearby participating centers is shared 4. List of studies with the participating sites is passed through
- 5. Subject grants authorisation to selected site to access
- the health summary to enable pre-screening to occur
- 6. Selected site receives health summary, including contact details, for pre-screening for specific study



Detailed use cases - data flows (3/3)



Study support PHR/EHRs to Study Database Systems or EDC (BUC10)

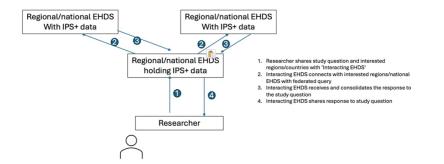


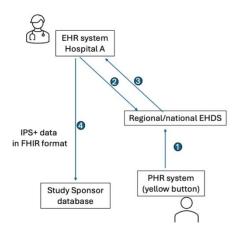
Observational studies/registries



Prospective clinical trials

A simplified flow noting the environments used in view of a RWE study is described in the following figure:





- 1. Subject approves electronic data sharing for prospective trial X 2. EHR system checks approval of subject A on data sharing for
- 3. Regional/national EHDS confirms approval
- 4. IPS+ data is pushed to the study sponsor study database (Note that the IPS+ push occurs more than once and incrementally, during the trial duration, so the sponsor database is kept up tot date with relevant clinical data.)



Overall technical considerations





Open architecture

Preference for highest interoperability



Security & GDPR

- Security following https://hl7.org/fhir/R4/security.html
- o Preference for minimal (ideally none) patient data in persistent storage



Adoption kit: xBundle for xShare IPS+ for research



Link: https://x-bundles.ehrexchange-format.eu/xb-3/main.html

Holds references to:

All use cases



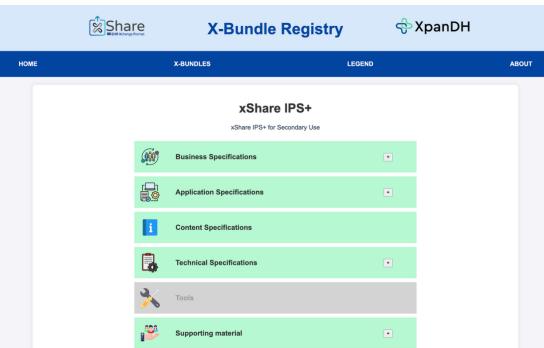
IPS+ implementation guide



IPS+ core data set



Base synthetic data







Demonstration

Jean-Sébastien Gosuin



Who we are





Curewiki

- Patient-first digital platform helping citizens discover and pre-screen for clinical trials.
- 38,740 patients and volunteers supported
- 5.83 million data points collected
- Al-driven eligibility engine for 24,000+ European studies

Vito (We Are)

- Flemish RTO enabling secure data exchange via the We Are datapod platform from Vitalink, the regional EHR repository.
- Connector for structured vaccination and prescription data
- Handles granular, patient-controlled consent

Together we demonstrate real-world implementation of citizen-initiated data sharing under EHDS standards.











How it works - End-to-end citizen-driven pre-screening flow Share

Citizen login

The citizen authenticates via IAM (Identity & Access Management), either directly in the Curewiki app or by selecting Curewiki in the WeAre App Store.

Survey completion

- The citizen completes the Curewiki pre-screening survey.
 - → Survey responses are securely pushed to the citizen's WeAre data pod.

Query for missing data

• The WeAre platform triggers a query to Vitalink for any missing clinical data (e.g. vaccination data, prescriptions).

Data retrieval with consent

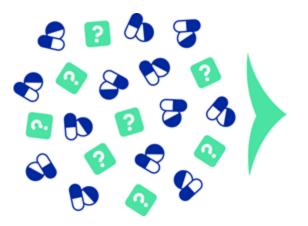
 With explicit citizen consent, the required clinical data are securely read from Vitalink via the WeAre platform and added to the data pod.

Eligibility assessment

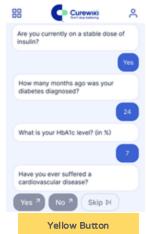
Curewiki, again with the citizen's consent, assesses the combined data (survey + Vitalink results) to
provide a personalised pre-screening recommendation — showing the citizen which trials they may be
eligible for.

the European Union

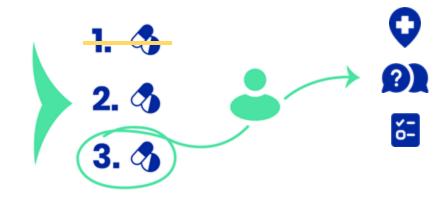
An intelligent interface between patients and research.



1) We parse 19,000 European studies and match their participation criteria with 9,000 unique questions in our database.



2) A chatbot asks the patient relevant questions to identify matching studies.



3) We generate a shortlist of studies the patient qualifies for, so they can make a choice.

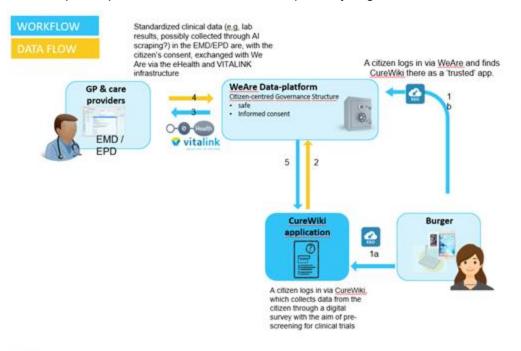
4) The patient picks a research project and is forwarded to the executing party.



Our xShare pilot



Business Use Case 2 (BUC2): Patient self-nomination as possibly eligible for a trial via the xShare Yellow Button



1a-b: A citizen logs in via the IAM (Identify & Access Management) and then completes the <u>CureWiki</u> survey, either by directly using the <u>CureWiki</u> app (a) or by selecting it in the WeAre app store (b)

- Data from the <u>CureWiki</u> survey are pushed to the WeAre pod
- A query for missing clinical data is carried out via VITALINK
- The required clinical data are, with the citizen's consent, read out by the WeAre data platform
- CureWiki, with the citizen's consent, accesses the clinical data in order to deliver a screening recommendation to the patient











Scope of the VITO-Curewiki pilot



Aspect	Details
Location	Flanders
Participants	50–100 citizens (no participant limit)
Data used	1) Vaccination data (standardised) 2) Prescriptions from past 3 months
Duration	6-month demonstration
Data standard	EEHRxF / IPS+
Governance	Citizen-driven consent via WeAre connector



What this achieves



For citizens

- Control over their own health data
- Transparent, secure sharing
- Instant feedback on clinical trial eligibility

For researchers

- Verified data (labs + medications)
- Fewer manual checks
- Faster, higher-quality recruitment

For xShare and EHDS

- Live validation of IPS-+ and EEHRxF standards
- Demonstrates real-world secondary use of data
- Scalable model for other regions and use cases

For public health actors

- Stronger medical innovation ecosystem through faster, datadriven research
- Reduced healthcare costs via more efficient study design, recruitment, and data reuse
- Better use of existing public EHR infrastructure for secondary research and policy evaluation
- Improved population health insights by securely linking real-world data with research outcomes





Thank you for the attention

